UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF ALABAMA

SHIRLEY F. BROWN, an individual,

Plaintiff,

vs.

Cook Incorporated; Cook Medical Incorporated; Cook Group Incorporated; Cook Medical, LLC,

Defendants.

JURY TRIAL DEMANDED

3:22-cv-55

COMPLAINT

Plaintiff Shirley F. Brown, by and through undersigned attorneys, hereby sues Defendants Cook Incorporated, Cook Medical Incorporated, Cook Group Incorporated, and Cook Medical, LLC, and alleges as follows:

PARTIES

1. Plaintiff Shirley F. Brown (hereinafter "Plaintiff") resides in, and is a citizen of, Lee County, Alabama.

2. Defendant Cook Incorporated was and is an Indiana corporation with its principal place of business located at 750 Daniels Way, Bloomington, Indiana 47402. At all times relevant to this action, Cook Incorporated designed, set specifications, manufactured, prepared, compounded, assembled, processed, promoted, marketed, distributed and/or sold the inferior vena cava filter ("IVC Filter") known as the Celect™ Vena Cava Set (hereinafter "Cook filter") to be implanted in patients throughout the United

States, including Alabama. At all times relevant hereto, Defendant Cook Incorporated was engaged in business in Alabama, has conducted substantial business activities, and derived substantial revenue from within the State of Alabama. This Defendant has also carried on solicitations or service activities in Alabama.

3. Defendant Cook Medical Incorporated is a wholly owned subsidiary of Defendant Cook Incorporated with its principal place of business located at 750 Daniels Way, Bloomington, Indiana 47402. Defendant Cook Medical Incorporated was and is an Indiana corporation authorized and/or doing business in the state of Alabama. At all times relevant to this action, Cook Medical Incorporated designed, set specifications, manufactured, prepared, compounded, assembled, processed, promoted, marketed, distributed and/or sold the IVC Filter known as the Celect™ Vena Cava Set to be implanted in patients throughout the United States, including Alabama. At all times relevant hereto, Defendant Cook Medical Incorporated was engaged in business in Alabama, has conducted substantial business activities, and derived substantial revenue from within the State of Alabama. This Defendant has also carried on solicitations or service activities in Alabama.

4. Defendant Cook Group Incorporated was and is an Indiana corporation having its principal place of business located at 750 Daniels Way, Bloomington, Indiana 47402. At all times relevant to this action, Cook Group Incorporated designed, set specifications, manufactured, prepared, compounded, assembled, processed, promoted, marketed, distributed and sold the IVC Filter known as the Celect™ Vena Cava Set to be implanted in patients throughout the United States, including Alabama. At all times relevant hereto, Defendant Cook Group Incorporated was engaged in business in Alabama,

has conducted substantial business activities, and derived substantial revenue from within the state of Alabama. This Defendant has also carried on solicitations or service activities in Alabama.

5. Defendant Cook Medical, LLC was and is an Indiana limited liability corporation with its principal place of business located at 750 Daniels Way, Bloomington, Indiana 47402 with its sole member being Cook Incorporated and maintains its principal place of business located at 750 Daniels Way, Bloomington, Indiana 47402. At all times relevant to this action, Cook Medical, LLC designed, set specifications, manufactured, prepared, compounded, assembled, processed, promoted, marketed, distributed and/or sold the IVC Filter known as the Celect™ Vena Cava Set to be implanted in patients throughout the United States, including Alabama. At all times relevant hereto, Cook Medical, LLC was registered to do business with the state of Alabama. At all times relevant hereto, Defendant Cook Medical LLC was engaged in business in Alabama, has conducted substantial business activities, and derived substantial revenue from within the state of Alabama. This Defendant has also carried on solicitations or service activities in Alabama.

6. Defendants Cook Incorporated, Cook Medical Incorporated, Cook Group Incorporated, and Cook Medical, LLC, shall be referred to herein individually by name or collectively as the "Cook Defendants."

7. At all times alleged herein, Cook Defendants include and included any and all parent companies, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors, and assigns and their

officers, directors, employees, agents, representatives, and any and all other persons acting on their behalf.

8. At all times herein mentioned, each of the Cook Defendants were the agents, servants, partners, predecessors in interest, and joint venturers of each other, and were at all times operating and acting with the purpose and scope of said agency, service, employment, partnership, joint enterprise, and/or joint venture.

JURISDICTION AND VENUE

9. Jurisdiction is proper in this court under 28 U.S.C.§ 1332(a)(1) because the Plaintiff and the Defendants are citizens of different states, and the amount in controversy exceeds seventy-five thousand dollars ($75,000.00), exclusive of interest and costs.

10. Venue is proper in this court under 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to the claim occurred within this judicial district and the Defendants regularly conduct business in this district.

GENERAL FACTUAL ALLEGATIONS

11. Plaintiff brings this case against the Cook Defendants because of the serious, life-threatening injury she has suffered as a result of the Cook Defendants' surgically implanted medical device, the Cook Celect filter, that was implanted at Orlando Health Orlando Regional Medical Center in Orlando, Florida on February 3, 2012.

12. Cook Defendants design, research, develop, manufacture, test, market, advertise, promote, distribute, and sell IVC filters, which are marketed and sold as both permanent and retrievable devices, purportedly to prevent recurrent pulmonary embolism. One such product is the Cook Celect IVC filter at issue in this case.

13. To date, there is no evidence to support the notion that IVC filters offer any clinical benefit to patients.

14. Cook Defendants sought Food and Drug Administration ("FDA") clearance to market the Cook Celect filter device and/or its components under Section 510(k) of the Medical Device Amendment.

15. On or about April 20, 2007, Defendants obtained FDA clearance to market the Cook Celect filter under Section 510(k) of the Medical Device Amendment.

16. Section 510(k) allows marketing of medical devices if the manufacturer claims the device is substantially equivalent to other legally marketed predicate devices, without formal review of the safety or efficacy of said device. The Cook Defendants claimed that the Celect filter was substantially equivalent to the Cook Gunther Tulip IVC filter, a medical device cleared by the FDA under the Section 510k process on October 18, 2000.

17. An IVC filter, like the Cook Celect filter, is a device ostensibly designed and intended to filter blood clots (called "thrombi") that would otherwise travel from the lower portions of the body to the heart and lungs, resulting in a pulmonary embolism (PE). IVC filters are marketed as being safe to implant, either temporarily or permanently, within the vena cava.

18. The inferior vena cava is a vein that returns blood to the heart from the lower portions of the body. In certain people, and for various reasons, thrombi travel from vessels in the legs and pelvis, through the vena cava and into the heart and lungs. These thrombi

can develop in the deep leg veins. This condition is called "deep vein thrombosis" or DVT. If the thrombi reach the lungs they are considered "pulmonary emboli" or PE.

19. The Celect filter is a retrievable filter and is alleged by Cook as being substantially similar to the Cook Defendants' Gunther Tulip filter, its predicate device.

20. The Celect filter has four (4) anchoring legs, or struts, for fixation within the IVC and eight (8) independent secondary struts claimed by Cook to improve self-centering and clot trapping.

21. On or about February 3, 2012, Plaintiff was implanted with a Cook Celect filter at Orlando Health Orlando Regional Medical Center in Orlando, Florida. The Cook Celect filter placed in Plaintiff was marketed and sold as appropriate for use as either a retrievable or permanent filter.

22. Plaintiff has suffered serious injury as a result of the implantation of the Cook Celect filter. Specifically, Plaintiff suffered multiple perforations of her IVC by the struts of her Cook Celect IVC filter. Struts are further perforating and abutting other organs in Plaintiff's body. Plaintiff is at risk for future progressive perforations by the Celect filter which could further injure adjacent organs, blood vessels, and structures, as well as fracturing of the IVC filter and migration of the Celect filter or pieces thereof. Plaintiff faces numerous health risks, including the risk of death. Plaintiff will require ongoing medical care and monitoring for the rest of her life. It is unknown if the filter can be retrieved by any means other than an open surgical procedure.

23. At all times relevant hereto, the Cook Celect filter was widely advertised and promoted by the Cook Defendants as safe and effective for prevention of recurrent pulmonary embolism.

24. At all times relevant to this complaint, the Cook Defendants knew or should have known that the Cook Celect IVC filter was defective and knew that defect was attributable to the design's failure to withstand the normal anatomical and physiological loading cycles exerted in vivo.

25. The Cook Defendants failed to disclose to physicians, patients, or Plaintiff that its retrievable IVC filters, including the Cook Celect filter, were subject to perforation through the IVC wall, fracture, and migration or the appropriate degree of risk of perforation and damage to the vena cava wall and surrounding organs, blood vessels, and structures.

26. At all times relevant hereto, the Cook Defendants continued to promote Cook's retrievable IVC filters, including the Cook Celect filter, as safe and effective even though the clinical trials that had been performed were not adequate to support long- or short-term safety or efficacy.

27. Cook Defendants concealed the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Cook retrievable IVC filters, including the Cook Celect filter, as aforesaid.

28. The failure of the Cook filter is attributable in part to the fact that the Cook retrievable IVC filters, including the Cook Celect filter, suffer from a design defect causing

the filters to be unable to withstand the normal anatomical and physiological loading cycles exerted in vivo.

29. At all times relevant hereto, the Cook Defendants failed to provide sufficient warnings and instructions that would have put Plaintiff and the general public on notice of the dangers and adverse effects caused by implantation of the Cook Celect filter, including, but not limited to, the design's failure to withstand the normal anatomical and physiological loading cycles exerted in vivo.

30. The Cook Celect filter was designed, manufactured, distributed, marketed, promoted, sold, and/or supplied by Cook Defendants and was marketed while defective due to the inadequate warnings, instructions, labeling, and/or inadequate testing in light of Cook Defendants' knowledge of the product's failure and serious adverse events.

31. At all times relevant hereto, the officers and/or directors of the Cook Defendants named herein participated in, authorized, and/or directed the production and promotion of the aforementioned products when they knew or should have known of the hazardous and dangerous propensities of said products, and thereby actively participated in the tortious conduct that resulted in the injuries suffered by Plaintiff.

FRAUDULENT CONCEALMENT

32. The Cook Defendants were under a continuing duty to disclose the true character, quality, and nature of the device that was implanted in Plaintiff, but instead they concealed them. The Cook Defendants remain under a continuing duty to disclose the true character, quality, and nature of the device that was implanted in Plaintiff, but instead they continue to conceal them. The Cook Defendants' conduct, as described in this complaint,

amounts to conduct purposely committed, which they must have realized was dangerous, heedless, and reckless, without regard to the consequences or the rights and safety of Plaintiff.

CORPORATE/VICARIOUS LIABILITY

33. At all times herein mentioned, the Cook Defendants were agents, servants, partners, aiders and abettors, co-conspirators, and/or joint venturers, and were at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy, and/or joint venture and rendered substantial assistance and encouragement to each other, knowing that their collective conduct constituted a breach of duty owed to the Plaintiff.

34. There exists and, at all times herein mentioned, there existed a unity of interest in ownership between the Cook Defendants such that any individuality and separateness between them have ceased and these Defendants are alter egos. Adherence to the fiction of the separate existence of these Defendants as entities distinct from each other will permit an abuse of the corporate privilege and would sanction a fraud and/or would not promote injustice.

35. At all times herein mentioned, the Cook Defendants were engaged in the business of, or were successors in interest to, entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing, and/or advertising for sale, and selling products for use by the

Plaintiff. As such, each Defendant is individually, as well as jointly and severally, liable to the Plaintiff for Plaintiff's damages.

36. At all times herein mentioned, the officers and/or directors of the Cook Defendants named herein participated in, authorized and/or directed the production, marketing, promotion and sale of the aforementioned products when they knew, or with the exercise of reasonable care and diligence should have known, of the hazards and dangerous propensities of said products, and thereby actively participated in the tortious conduct that resulted in the injuries suffered by the Plaintiff.

COUNT I
VIOLATIONS OF ALABAMA EXTENDED MANUFACTURERS LIABILITY DOCTRINE (AEMLD)

37. Plaintiff incorporates by reference all preceding paragraphs.

38. Prior to, on and after the date the Cook Celect filter was implanted in Plaintiff and at all relevant times, Cook Defendants designed, distributed, manufactured, sold, and marketed the Cook Celect filter for use in the United States.

39. At all times herein mentioned, Cook Defendants designed, distributed, manufactured, marked, and sold the Cook Celect filter such that it was dangerous, unsafe, and defective due to design, manufacture, and lack of adequate warnings.

40. The Cook Celect filter contained all of these defects when it left the Cook Defendants' possession.

41. At the time of the events set forth herein, the Cook Celect filter was expected to and did reach the Plaintiff without substantial change in the condition in which the product was sold by the Cook Defendants.

42. Plaintiff is informed and believes, and on that basis alleges that the Cook Celect filter contained a manufacturing defect in that it differed from the manufacturer's design or specifications, or from other typical units of the same product line.

43. Prior to the dates on which the Cook Celect filter was implanted in Plaintiff, Cook Defendants manufactured, distributed, and sold the Cook Celect filter.

44. The Cook Celect filter had potential risks and side effects that were known or knowable to the Cook Defendants by the use of scientific knowledge available before, at, and after the manufacture, distribution, and sale of the Cook Celect filter.

45. Cook Defendants knew or should have known of the defective condition, characteristics, and risks associated with the Cook Celect filter, as previously set forth herein.

46. Said defective conditions included, but were not limited to, the Cook Celect filter posing a significant and higher risk than other similar devices of device failure (fracture, migration, tiling, extreme clotting and thrombosis, and perforation of the vena cava wall) resulting in death and/or serious injuries and that certain conditions or post-implant procedures, such as morbid obesity or open abdominal procedures, could affect the safety and integrity of the device, among other things.

47. The Cook Celect filter was in a defective condition that was unreasonably and substantially dangerous to any other user or ordinary consumer implanted with the Cook Celect filter, such as Plaintiff, when used in an intended or reasonably foreseeable way.

48. Such ordinary consumers, including Plaintiff, would not and could not have

recognized or discovered the potential risks and side effects of the Cook Celect filter, as set forth herein.

49. The warnings and directions provided with the Cook Celect filter by Cook Defendants failed to adequately warn of the potential risks and side effects of the Cook Celect filter, which risks were known or were reasonably scientifically knowable to Cook Defendants, but not known or recognizable to ordinary consumers, such as Plaintiff or her treating doctors.

50. The Cook Celect filter was expected to and did reach Plaintiff without substantial change in its condition, labeling, or warnings as manufactured, distributed, and sold by Cook Defendants.

51. Plaintiff and Plaintiff's physician used the Cook Celect filter in the manner in which it was intended to be used, making such use reasonably foreseeable to Cook Defendants.

52. Cook Defendants' lack of sufficient instructions or warnings prior to, on, and after the date Plaintiff was implanted with the Cook Celect filter was a substantial factor causing Plaintiff's injuries and damages.

53. Cook Defendants' design, manufacture, marketing, promotion, and sale of the Cook Celect filter were a substantial factor in causing Plaintiff's injuries and damages.

54. As a direct and proximate result of Cook Defendants' defective design, manufacture, marketing, and sale of the Cook Celect filter prior to and on the date Plaintiff used the Cook Celect filter, Plaintiff suffered damages herein described.

COUNT II

NEGLIGENCE

55. Plaintiff realleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

56. At all times relevant to this cause of action, the Cook Defendants were in the business of designing, developing, setting specifications, manufacturing, marketing, promoting, selling, and distributing Cook IVC filters including the Cook Celect IVC filter.

57. The Cook Defendants designed, manufactured, marketed, inspected, labeled, promoted, distributed and sold the Cook Celect filter that was implanted in Plaintiff.

58. The Cook Defendants had a duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution and sale of Cook IVC filters, including the Celect filter, so as to avoid exposing others to foreseeable and unreasonable risks of harm.

59. The Cook Defendants knew or reasonably should have known that the Cook Celect filter was dangerous or was likely to be dangerous when used in its intended or reasonably foreseeable manner.

60. At the time of manufacture and sale of the Cook Celect filter (2007 until 2015), the Cook Defendants knew or should have known that the Cook Celect filter was designed and manufactured so as to present an unreasonable risk of the device tilting and/or perforating the vena cava wall.

61. At the time of manufacture and sale of the Cook Celect filter (2007 until 2015), the Cook Defendants knew or should have known that using the Cook Celect filter in its intended use or in a reasonably foreseeable manner created a significant risk of a

patient suffering severe health side effects, including, but not limited to: hemorrhage; pericardial effusion; cardiac tamponade; cardiac arrhythmia and other symptoms similar to myocardial infarction; perforations of tissue, vessels, and organs; and other severe personal injuries and diseases, which are permanent in nature, including, but not limited to, death, physical pain and mental anguish, scarring and disfigurement, diminished enjoyment of life, continued medical care and treatment due to chronic injuries/illness proximately caused by the device; and the continued risk of requiring additional medical and surgical procedures including general anesthesia, with attendant risk of life threatening complications.

62. The Cook Defendants knew or reasonably should have known that consumers of the Cook Celect filter would not realize the danger associated with using the device in its intended use and/or in a reasonably foreseeable manner.

63. The Cook Defendants breached their duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution and sale of the Cook Celect filter in, among others, the following ways:

a. Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the burden of taking safety measures to reduce or avoid harm;

b. Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the likelihood of potential harm from other devices available for the same purpose;

c. Failing to use reasonable care in manufacturing the product and producing a product that differed from their design or specifications or from other typical units from the same production line;

d. Failing to use reasonable care to warn or instruct, including pre and post-sale, Plaintiff, Plaintiff's physicians, Plaintiff's agents or the general health care community about the Cook Celect filter's substantially dangerous condition or about facts making the product likely to be dangerous;

e. Failing to perform reasonable pre and post-market testing of the Cook Celect filter to determine whether or not the product was safe for its intended use;

f. Failing to provide adequate instructions, guidelines, and safety precautions, including pre and post-sale, to those persons to whom it was reasonably foreseeable would prescribe, use, and implant the Cook Celect filter;

g. Advertising, marketing and recommending the use of the Cook Celect filter, while concealing and failing to disclose or warn of the dangers known by Defendants to be connected with and inherent in the use of the Cook Celect filter;

h. Representing that the Cook filter was safe for its intended use when in fact, the Cook Defendants knew and should have known the product was not safe for its intended purpose;

i. Continuing manufacture and sale of the Cook Celect filter with the knowledge that said product was dangerous and not reasonably safe;

j. Failing to use reasonable and prudent care in the design, research, manufacture, and development of the Cook Celect filter so as to avoid the risk of serious harm associated with the use of the Cook Celect filter;

k. Advertising, marketing, promoting and selling Cook Celect filter for uses other than as approved and indicated in the product's label;

l. Failing to establish an adequate quality assurance program used in the manufacturing of the Cook Celect filter; and,

m. Failing to establish and maintain an adequate post-market surveillance program.

n. Failing to conduct patient studies to determine whether the Cook Celect filter offers a clinical benefit to patients.

o. Upon learning that IVC filters do not provide any clinical benefit to patients, defendants continued to sell its IVC filters, failed to pull them off the market, failed to notify the medical community to stop implanting its filters and failed to notify patients implanted with filters to have them removed.

64. A reasonable manufacturer, distributor, or seller under the same or similar circumstances would not have engaged in the aforementioned acts and omissions.

65. As a direct and proximate result of the foregoing negligent acts and omissions by the Cook Defendants, Plaintiff has suffered a serious medical complication for which the solution and ultimate economic loss is yet to be determined.

COUNT III
FRAUD

66. Plaintiff realleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

67. At all times relevant to this cause of action, the Cook Defendants were in the business of designing, developing, setting specifications for, licensing, manufacturing, preparing, packaging, maintaining, labeling, compounding, assembling, processing, promoting, selling, distributing, and marketing Cook Gunther Tulip IVC filters and Cook Celect IVC filters.

68. At the time Plaintiff was implanted the Cook Defendants developed, tested, designed, manufactured, inspected, labeled, promoted, distributed, marketed, and sold into the stream of commerce the Cook Celect IVC filter placed in her body.

69. At all times relevant to this action, the Cook Defendants designed, researched, developed, manufactured, tested, labeled, inspected, advertised, promoted, marketed, sold, and distributed into the stream of commerce the Gunther Tulip and Celect IVC filters for use as a surgically implanted device used to prevent pulmonary embolisms

and for uses other than as approved and indicated in the product's instructions, warnings, and labels.

70. The Cook Defendants falsely and fraudulently represented to Plaintiff, her physicians, and other members of the general public, that the Cook Celect IVC filter:

a. Has been proven to effectively prevent pulmonary embolism;

b. Was self-centering and offered efficient clot trapping;

c. Was designed to minimize the most common filter complications;

d. The anchors on the filter created secure, atraumatic attachments to the caval wall;

e. Provided enhanced retrievability giving an extended time for retrieval; and,

f. Could safely stay in place permanently in the body.

71. In the Clinical Study section of the Instructions for Use provided to the physicians who were implanting the Cook Celect IVC filter, including the filter implanted in the Plaintiff, the Cook Defendants states a clinical study involved a 74 patient cohort, with follow-up conducted at 1 month (60 of 69 possible patients), 3 months (50 of 58 possible patients) and 6 months (37 of 41 possible patients) consisting of clinical exam and imaging by X-ray and duplex ultrasound, no device related major adverse events (defined as hemorrhage, perforation, death, occlusion, filter fracture or significant filter migration) occurred.

72. The representations by the Cook Defendants were, in fact, false. The true facts were that the Cook Celect IVC filter is not safe for long term/permanent surgical implantation for said purposes, it has not been proven the filter effectively prevents

pulmonary embolism; the filter presents a high risk of perforation through the caval wall, the filter has a high risk for fracture, and the filter is not safe for permanent placement in the body. In the clinic study that was presented to physicians through the instructions for use, the IFU gives a false sense of safety by reporting on a subset of OUS patients regarding high rates of successful retrieval rates and no complications, which has been shown to be incorrect. The retrieval rates listed give a false sense of safety when the OUS study did not address safety, and falsified complication and perforation rates. The Celect filter was and is, in fact, dangerous to the health and body of Plaintiff.

73. When the Cook Defendants made the aforesaid representations, and others, they knew them to be false, and those representations were made by the Cook Defendants with the intent to defraud and deceive Plaintiff and her physicians, and with the intent to induce Plaintiff and her physicians to act in the manner herein alleged, *i.e.*, to use the Cook Celect IVC filter in surgery.

74. As a direct and proximate result of the foregoing negligent acts and omissions by the Cook Defendants, Plaintiff has suffered a serious medical complication for which the solution and ultimate economic loss is yet to be determined.

COUNT IV
NEGLIGENT MISREPRESENTATION

75. Plaintiff realleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

76. At all times relevant to this cause, and as detailed herein, the Cook Defendants negligently provided Plaintiff, Plaintiff's health care providers, and the general

medical community with false or incorrect information, or omitted or failed to disclose material information concerning Cook IVC filters and the Cook Celect filter; including, but not limited to, misrepresentations relating to the safety, efficacy, failure rate and approved uses of the Cook IVC filter.

77. The Cook Defendants falsely represented to Plaintiff, her physicians, and other members of the general public, that the Cook Celect IVC filter:

a. Was proven to be hemodynamically effective;

b. Has been proven to effectively prevent pulmonary embolism;

c. Was self-centering and offered efficient clot trapping;

d. Was designed to minimize the most common filter complications;

e. The anchors on the filter created secure atraumatic attachments to the caval wall;

f. Provided enhanced retrievability giving an extended time for retrieval; and

g. Could safely stay in place permanently in the body.

78. In the Clinical Study section of the Instructions for Use provided to the physicians who were implanting the Cook Celect IVC filter, including the filter implanted in the Plaintiff, the Cook Defendants states a clinical study involved a 74 patient cohort, with follow-up conducted at 1 month (60 of 69 possible patients), 3 months (50 of 58 possible patients) and 6 months (37 of 41 possible patients) consisting of clinical exam and imaging by X-ray and duplex ultrasound, no device related major adverse events (defined as hemorrhage, perforation, death, occlusion, filter fracture or significant filter migration) occurred.

79. The representations by the Cook Defendants were, in fact, false. The true facts were that the Cook Celect IVC filter is not safe for long term/permanent surgical implantation for said purposes, it has not been proven the filter effectively prevents pulmonary embolism; the filter presents a high risk of perforation through the caval wall, the filter has a high risk for fracture, and the filter is not safe for permanent placement in the body. In the clinic study that was presented to physicians through the instructions for use, the IFU gives a false sense of safety by reporting on a subset of OUS patients regarding high rates of successful retrieval rates and no complications, which has been shown to be incorrect. The retrieval rates listed give a false sense of safety when the OUS study did not address safety, and falsified complication and perforation rates. The Celect filter was and is, in fact, dangerous to the health and body of Plaintiff.

80. The information distributed by the Cook Defendants to the public, the medical community and Plaintiff's health care providers, including reports, press releases, advertising campaigns, labeling materials, print advertisements, commercial media containing material representations, was false and misleading, and contained omissions and concealment of truth about the dangers of the use of the Cook IVC filters, including the Cook Celect Filter. The Cook Defendants made the foregoing misrepresentations knowing that they were false and/or without reasonable basis in fact. These materials included instructions for use and warning document that was included in the packaging of the Cook Celect filter that was implanted in Plaintiff.

81. The Cook Defendants' intent and purpose in making these misrepresentations was to deceive and defraud the public and the medical community,

including Plaintiff's health care providers; to gain the confidence of the public and the medical community, including Plaintiff's health care providers; to falsely assure them of the quality of the Cook IVC filters, including the Celect IVC filter and its fitness for use; and to induce the public and the medical community, including Plaintiff's healthcare providers to request, recommend, prescribe, implant, purchase, and continue to use Cook IVC filters, including the Cook Celect filter.

82. In reliance upon the false and negligent misrepresentations and omissions made by the Cook Defendants, Plaintiff, Plaintiff's health care providers and the Plaintiff's agents were induced to, and did use the Cook Celect filter, thereby causing Plaintiff to sustain severe personal injuries.

83. The Cook Defendants knew and had reason to know that Plaintiff, Plaintiff's health care providers, and the general medical community did not have the ability to determine the true facts intentionally and/or negligently concealed and misrepresented by the Cook Defendants, and would not have prescribed and implanted same, if the true facts regarding the device had not been concealed and misrepresented by the Cook Defendants.

84. The Cook Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects in the form of dangerous injuries and damages to persons who are implanted with the Cook filter.

85. At the time Cook Defendants failed to disclose and misrepresented the foregoing facts, and at the time Plaintiff used the Cook Celect filter, Plaintiff, Plaintiff's

health care providers and the Plaintiff's agents were unaware of said Cook Defendants' negligent misrepresentations and omissions.

86. Plaintiff, Plaintiff's health care providers, the Plaintiff's agents and general medical community reasonably relied upon misrepresentations and omissions made by the Cook Defendants where the concealed and misrepresented facts were critical to understanding the true dangers inherent in the use of the Cook Celect filter.

87. Plaintiff, Plaintiff's health care provider's and Plaintiff's agents' reliance on the foregoing misrepresentations and omissions by Cook Defendants' were the direct and proximate cause of Plaintiff's injuries as described herein.

COUNT V
VIOLATIONS OF THE ALABAM DECEPTIVE TRADE PRACTICES ACT (ADTPA)

88. Plaintiff herby incorporates by reference all preceding paragraphs;

89. Cook Defendants engaged in conduct in violation of ADTPA, including but not limited to those enumerated in Sections 8-19-5 (2), (3), (5), (7), and (27).

90. Plaintiff is in the class of persons the ADTPA was and is designed to protect.

91. As a result of Cook Defendants' violations of ADTPA, Plaintiff suffered injuries and damages.

COUNT VI
PUNITIVE DAMAGES

92. Plaintiff realleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

93. The actions and inactions of all the Defendants, and or alternatively the employees or agents of Defendants, and their predecessors-in-interest, whether taken separately, or together, were of such a character as to constitute a pattern or practice of intentional wrongful conduct and/or malice resulting in the injury and damages of Plaintiff Shirley F. Brown.

94. More specifically, Defendants, or alternatively the employees or agents of Defendants, and their predecessors-in-interest, consciously and/or deliberately concealed risks associated with their product and nevertheless proceeded with conscious indifference to the rights, safety, and welfare of Plaintiff Shirley F. Brown by failing to act to disclose these risks to her or her healthcare professionals.

95. Defendants are guilty of oppression, fraud, and/or malice, express or implied for which they should be held liable in punitive damages to Plaintiff Shirley F. Brown.

PRAYER FOR DAMAGES

WHEREFORE, Plaintiff, Shirley F. Brown, prays for relief on the entire complaint, as follows:

a. Judgment to be entered against all Defendants on all causes of action of the Complaint, including but not limited to:

   1. Pain and suffering;

   2. Mental anguish in the past and which, in reasonable probability, she will sustain in the future; and,

   3. Reasonable and necessary medical expenses for treatment received in the past and, based upon reasonable medical probability, the reasonable medical expenses she will need in the future;

b. Plaintiff be awarded full, fair, and complete recovery for all claims and causes of action relevant to this action;

c. Plaintiff be awarded all appropriate costs, fees, expenses, and pre-judgment and post-judgment interest on the judgments entered in Plaintiff's behalf; and,

d. Such other relief the court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury on all issues.

DATED January 25, 2022.

Respectfully submitted,

GOLDASICH, VICK & FULK

By:/s/
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Attorneys for Plaintiff Shirley F. Brown

CERTIFICATE OF SERVICE

I hereby certify that on January 25, 2022, I hand delivered the attached document to the Clerk's Office for filing and transmittal of a Notice of Electronic Filing on all CM/ECF registrants.

/s/ Nathan C. VanDerVeer